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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,409

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Shik Chi Tsang

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER

BASS, DIRK R

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

05/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,409	Applicant(s) TSANG ET AL.	
	Examiner DIRK BASS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-50 is/are pending in the application.
- 4a) Of the above claim(s) 2-18 and 26-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/13/2006, 12/21/ 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of group I, claims 1 and 20-25 in the reply filed on April 28, 2009 is acknowledged. The traversal is on the ground(s) that all claims "should be considered together as they are all, in essence, based on a common inventive concept". This is not found persuasive because according to Tan et al., US 6548264, the common linking feature found between all groups for restriction, i.e. compositions entrapping catalytically active species, is well known in the art. Because the common linking feature fails to make a contribution over the prior art, the groups for restriction are found to lack unity.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant's preliminary amendment, filed May 15, 2009, is acknowledged. Claim 20 is amended. Claims 1 and 20-25 are considered on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, it is unclear in separating step (b) which solvent is separated into a second composition. For the purposes of examination, the examiner is interpreting the second composition to comprise the first solvent, as recited in claim 20.

Claim 24 recites the limitation "said supernatant" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1, 20-22, and 24** are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cavalli et al., "Solid lipid nanoparticles as carriers of hydrocortisone and progesterone complexes with β -cyclodextrins", *International Journal of Pharmaceutics*, vol. 182, pgs. 59-69 (1999) (Cavalli).

Regarding claims 1 and 20, Cavalli discloses a method of measuring the partition coefficient of a compound (see "hydrocortisone" or "progesterone" in abstract) between two immiscible solvents (see Sections 1 and 2.4) comprising:

- a. Providing a composition which contains said compound and comprises nanoparticles (see "solid lipid nanoparticles (SLN)" in abstract) having a porous surface (see "lipid matrix", Section 3.4) and a first solvent (see "water", Section 2.4), wherein a second solvent is absorbed into the pores of the nanoparticles (see "stearic acid", Section 2.7) and wherein said first and second solvents are immiscible;
- b. Separating the product of step (a) into two components, the first comprising the nanoparticles and the second comprising the first solvent (see Section 2.4); and
- c. Determining the partition coefficient from the partition of the compound between said first and second components (see Section 2.4).

Regarding claims 21-22, Cavalli discloses a method wherein step (c) comprises determining the amount of a bioactive drug molecule in said first solvent (see "hydrocortisone" or "progesterone" in abstract and Section 2.4).

Regarding claim 24, Cavalli discloses a method wherein step (c) comprises recording the UV-visible spectrum of said supernatant solution (see Section 2.9).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 23 and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavalli et al., "Solid lipid nanoparticles as carriers of hydrocortisone and progesterone complexes with β -cyclodextrins", *International Journal of Pharmaceutics*, vol. 182, pgs. 59-69 (1999) (Cavalli).

Regarding claim 23, while Cavalli fails to explicitly disclose a method wherein step (b) is performed by filtration, centrifugation, or magnetic separation, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize any of said separation methods, since the examiner takes official notice of the equivalence of said separation methods and the freeze-drying method of Cavalli (see section 2.6) for their use in the separations art and the selection of any of these known equivalents to separate a composition would be within the level of ordinary skill in the art (see MPEP 2144.06).

Regarding claim 25, while Cavalli fails to explicitly disclose a method further comprising shaking the composition, it would have been obvious to one having ordinary skill in the art at the time of the invention to shake said composition, since the examiner takes official notice of the equivalence of said shaking and stirring disclosed by Cavalli (see Section 2.4) for their use in the mixing art and the selection of any of these known equivalents to mix a composition would be within the level of ordinary skill in the art (see MPEP 2144.06).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

/DRB/
Dirk R. Bass